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EXAMINER

HARRIS, A

ART UNIT

PAPER NUMBER

1642

13

DATE MAILED: 03/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/285,292

Applicant(s)
Albertson et al.

Examiner
Alana M. Harris, Ph. D.

Group Art Unit
1642



☒ Responsive to communication(s) filed on November 30, 2000.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-70 is/are pending in the application.

Of the above, claim(s) 33-70 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-32 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I (claims 1-8, 13-24 and 28-32) in Paper Number 127 (filed November 30, 2000) is acknowledged. The traversal is on the grounds that the restriction between Groups I, II and III, between Groups IV, V and VI and between Groups VII, VIII and IX is legally improper as set forth in Paper Number 9 (mailed June 19, 2000). Further, Applicants assert that the examination of Groups I-IX would not impose a serious burden. This is found to be partially persuasive.

Upon reconsideration claims 1-32 will be joined as Group I, claims 33-50 will be joined as Group II and claims 51-70 will be joined as Group III as listed in paragraph two. The claims of the three newly recited Groups in paragraph number 2 necessitate different searches in the U.S. Patent shoes. Further, classification of subject matter is merely one indication of the burdensome nature of the search involved. Clearly different searches and issues are involved in the examination of each group. For these reasons the restriction requirement is deemed to be proper and is adhered to.

The requirement is therefore made FINAL.

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2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-32, drawn to a method of detecting a predisposition to cancer comprising detecting and measuring the level of *CYP24*, classified in class 435, subclass 6.
 - II. Claims 33-50, drawn to a method of treating cancer comprising detecting *CYP24*, classified in class 424, subclass 1.37.
 - III. Claims 51-70, drawn to a method of screening a test agent comprising detecting the level of *CYP24*, classified in class 514, subclass 2.

3. The inventions are distinct, each from the other because of the following reasons:

The methods of Groups I-III differ in the method objectives, method steps and parameters and in the reagents used.

Inventions of Groups I-III are related as processes of use. The inventions can be shown to be distinct. In the instant case the processes of all the method Groups do involve *CYP24*, however these processes utilize different assays that yield different qualitative and quantitative results.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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4. Claims 1-70 are pending.

Claims 33-70, drawn to non-elected inventions, are withdrawn from examination.

Claims 1-32 are examined on the merits.

Claim Rejections - 35 U.S.C. § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting a predisposition to breast cancer in tissue cultured cell lines, comprising detection of *CYP24* copy number, RNA and protein, does not reasonably provide enablement for a method of detecting a predisposition to any and all cancers in animal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claim 1 broadly claims a method of detecting a predisposition to cancer of any type in an animal. There are references provided within the "Brief Description of the Drawings", pages 17 and 18 that list comparative genomic hybridization (CGH) measurement and gene expression measurement on the breast cancer tumor cell lines, S21, S59, MCF7 and BT474. However, the specification does not provide support for this methodology in any cancer type other than breast

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cancer. While it is clear that *CYP24* is associated with breast cancer, there is no correlation between *CYP24* and other types of cancer. The specification is merely speculating in this regard. One of skill in the art knows that the very nature of cancer, notwithstanding differences in histology, grade and type is an unpredictable and multifactorial disease. Even though the claimed methodology may be applicable to other types of cancer it is known that some routine diagnostic procedures may not produce firm diagnoses. Thus, absent any objective evidence to show that *CYP24* is found in cancer other than breast, it would require undue experimentation to make and use the invention.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 3 and 21 are vague and indefinite in the recitation "...copy number is measured...". It is not clear as to what is specifically being measured. Is one skilled in the art looking for the gain or loss of DNA sequences, such as deletions, duplications or amplifications?

b. The recitation "...an increased level of *CYP24*..." in claims 6, 9 and 23 is vague and indefinite. What amount of RNA or protein is deemed increased? Would it be 5% or 25% more

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that what is observed in the comparative sample? Accordingly, it is impossible to determine the metes and bounds of the claims.

c. Claims 15 and 30 are vague and indefinite in the recitation "...statistically significant difference." How is this statistical difference defined?

d. The recitation "...a reduced survival expectancy." in claims 18, 23, 25 is vague and indefinite. How is reduced defined and what sample population is one of skill in the art to compare expectancy levels?

e. Claim 18 is vague and indefinite because the claims does not reveal how the survival expectancy is to be estimated or evaluated. The claim only discloses how *CYP24* is to be detected.

Conclusion

9. Claims 1-32 are free of the art.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris whose telephone number is (703)306-5880. The examiner can normally be reached on Monday through Friday from 6:30 am to 3:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703)308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703)308-0196.

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Alana M. Harris, Ph.D.
Patent Examiner, Group 1642
March 12, 2001

A handwritten signature in cursive script that reads "Sheila J. Huff".

**SHEELA HUFF
PRIMARY EXAMINER**